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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,234	09/20/2001	Howard J. Jacob	13482-002001	5858

26191 7590 02/26/2003

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,234

Applicant(s)

JACOB ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-6, 21 and 25, drawn to a method for identifying relationships among physiological determinants within a set of physiological determinants, classified in class 702, subclass 27.
 - II. Claims 7-9 and 21, drawn to a method of assessing the physiological response of an organism or organisms to a challenge, classified in class 702, subclass 27.
 - III. Claims 10, 11 and 21, drawn to a method of assessing the change in physiological state of an organism or organisms over time, classified in class 702, subclass 27.
 - IV. Claims 12-14 and 26, drawn to a method of partitioning organisms into homogeneous subclasses based on expression profile and a method for modifying or supplementing actuarial tables for life and health insurance, classified in class 702, subclass 19. If this Group is elected, then the below summarized species election is also required.
 - V. Claims 15 and 16, drawn to a method of assigning an organism to a homogeneous subclass of organisms based on physiological profile, classified in class 702, subclass 19.

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- VI. Claims 17, 18 and 21, drawn to a method of determining the contribution(s) of a gene or genes to a physiological process in an organism, classified in class 702, subclass 19.
- VII. Claims 19 and 20, drawn to computer-readable medium comprising a physiological profile, classified in class 702, subclass 19.
- VIII. Claim 22, drawn to a method of determining whether a hypertensive patient is a modulator or non-modulator based on a gene encoding renin, classified in class 702, subclass 19.
- IX. Claim 23, drawn to a method of determining whether a patient is at risk for hypotension following administration of a vasoconstrictor agent based on the allelic status of a gene encoding NOSII in a patient, classified in class 702, subclass 19.
- X. Claim 24, drawn to a method of determining whether a patient is at risk for hypotension following administration of a vasoconstrictor agent based on the allelic status of a gene encoding NOSIII in a patient, classified in class 702, subclass 19.

SPECIE ELECTION REQUIREMENT FOR GROUPS IV:

- 2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: Methods involving actuarial tables.

Species B: Generic methods of partitioning organisms.

3. The cited species above are generally separately analyzed and published, thus, document the undue search burden if searched together. Thus, applicants are required to select a species listed above.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12-14 are generic to the above species.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The inventions of Groups I-X are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations and active steps therein. For Group I, the critical limitation is a method for identifying relationships among physiological determinants within a set of physiological determinants. For Group II, the critical limitation is a method of assessing the physiological response of an organism or organisms to a challenge. For Group III, the critical limitation is a method of assessing the change in physiological state of an

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organism or organisms over time. For Group IV, the critical limitation is a method of partitioning organisms into homogeneous subclasses based on expression profile and a method for modifying or supplementing actuarial tables for life and health insurance. For Group V, the critical limitation is a method of assigning an organism to a homogeneous subclass of organisms based on physiological profile. For Group VI, the critical limitation is a method of determining the contribution(s) of a gene or genes to a physiological process in an organism. For Group VII, the critical limitation is a computer-readable medium comprising physiological profile. For Group VIII, the critical limitation is a method of determining whether a hypertensive patient is a modulator or non-modulator based on a gene encoding renin. For Group IX, the critical limitation is a method of determining whether a patient is at risk for hypotension following administration of a vasoconstrictor agent based on the allelic status of a gene encoding NOSII in a patient. For Group X, the critical limitation is a method of determining whether a patient is at risk for hypotension following administration of a vasoconstrictor agent based on the allelic status of a gene encoding NOSIII in a patient. It is acknowledged that the commonality of these inventions is the data used to derived relationships based on physiological or expression profiles. However, the different intended goals and supporting active steps of each method cause them to be distinct. Further, the critical limitation of a gene encoding NOSII is distinct from a gene encoding NOSIII. It is also noted that the computer readable medium of Group VII is reasonably utilized in a variety of other method Groups discussed above. Therefore, the completely distinct critical limitations and active steps of each Group of the inventions support the undue search burden if they were examined together. Additionally, the methods of generating physiological and expression profile data have been most commonly, albeit not

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always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

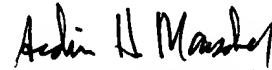
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

14. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/24/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER